

National Environmental  
Laboratory **Accreditation**  
Conference

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# ACCREDITING AUTHORITY

PROPOSED

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***N O T E: Additions (double-underlined) and deletions (struck through) to the approved standards being considered by the Accrediting Authority Committee for vote at the next Annual Meeting are marked as in this note.***

## **6.0 ACCREDITING AUTHORITY**

### **6.1 INTRODUCTION**

The standards in this Chapter define the process and criteria that will be used by the National Environmental Laboratory Accreditation Program (NELAP) to determine whether accrediting authorities applying for NELAP recognition meet the standards required for such recognition.

Chapter six is structured so that the requirements of the International Organization for Standardization/the International Electrotechnical Commission (ISO/IEC) Guide 58: Calibration and testing laboratory accreditation systems-General requirements for operation and recognition, 1993 are incorporated into the requirements for an accrediting authority to be NELAP-recognized.

Chapter six addresses most of the requirements of ISO/IEC Guide 58. All NELAP-recognized accrediting authorities are required to administer an environmental laboratory accreditation program that meets the requirements contained in the National Environmental Laboratory Accreditation Conference (NELAC) standards, Chapter six. Those ISO/IEC Guide 58 requirements not addressed in Chapter six are addressed in the NELAC standards, Chapters two through five. Since Chapter six requires an accrediting authority to administer an environmental laboratory accreditation program that requires laboratories to meet the standards set forth in the NELAC standards, Chapters two through six, all the requirements of ISO/IEC Guide 58 will be met by a NELAP-recognized accrediting authority. In most cases, the ISO/IEC requirements, contained in Chapter six or elsewhere in the NELAC standards are not direct quotations from the ISO/IEC guidance document.

### **6.2 GENERAL PROVISIONS**

- a) In all cases, accrediting authorities are governmental organizations at the territory, state or federal levels.
- b) A territorial, state or federal entity shall designate the appropriate agencies or departments as its designated NELAP-recognized accrediting authorities for the fields of testing for which NELAP recognition is being sought.
- c) A NELAP-recognized accrediting authority shall not delegate authority for granting, maintaining, suspending or revoking a laboratory's NELAP accreditation to an outside person or body. Portions of the accreditation process may be contracted out when the accrediting authority follows the provisions of subsections 6.3.3.1.2 and 6.3.3.1.3 (b)(3); however, the authority to grant, maintain, suspend or revoke NELAP accreditation must remain with the accrediting authority.
- d) The procedures under which a NELAP-recognized accrediting authority operates shall be administered in an impartial and non-discriminatory manner. The accrediting authority also shall require accredited laboratories to maintain impartiality and integrity. An accrediting authority shall have no rules, regulations, procedures or practices that:
  - 1) restrict the size, large or small, of any laboratory seeking accreditation;

- 2) require membership or participation in any laboratory or other professional association;
  - 3) impose any financial conditions or restrictions for participation in the accreditation program other than the fees authorized by territorial, state or federal law; and
  - 4) conflict with any territorial, state or federal laws governing discrimination.
- e) Accrediting authorities and their contractors shall confine their requirements, assessments and decision making processes for a NELAP accredited laboratory to those matters specifically related to the fields of testing of the NELAP accreditation being sought by a laboratory.
- f) If the NELAP insignia is used on general literature such as brochures, letterheads and business cards, a NELAP-recognized accrediting authority shall accompany the display of the NELAP insignia with at least the phrase "NELAP-recognized".
- g) Accrediting authorities, within the scope and applicability of their prevailing rules and regulations, shall establish one or more technical committees for assistance in interpretation of requirements and for advising the accrediting authority on the technical matters relating to the operation of its environmental laboratory accreditation program. When such committees are established, the accrediting authority shall have
- 1) formal rules and structures for the appointment and operation of committees involved in the accreditation process and such committees shall be free from any commercial, financial, and other pressures that might influence decisions, or
  - 2) a structure where committee members are chosen to provide relevant competent technical support and impartiality through a balance of interests where no single interest predominates, and
  - 3) a mechanism for publishing interpretations and recommendations made by these committees.
- h) Unless the contrary is clearly indicated, all references in this Chapter to singular nouns include the plural noun, and all references to plural nouns include the singular, for example, "area of responsibility" also includes multiple "areas of responsibility."

#### **6.2.1 Reciprocity**

- a) Except as noted in this subsection, NELAP-recognized secondary accrediting authorities shall grant accreditation to laboratories accredited by any other NELAP-recognized primary accrediting authority. Such reciprocal NELAP accreditation shall be granted on a laboratory-by-laboratory basis. The NELAP-recognized secondary accrediting authority shall consider only the current certificate of accreditation issued by the NELAP-recognized primary accrediting authority.
- b) When granting reciprocal accreditation to a laboratory, the NELAP-recognized secondary accrediting authority shall:
- 1) grant reciprocal accreditation for only the fields of testing, methods and analytes for which the laboratory holds current primary NELAP accreditation, and
  - 2) grant reciprocal accreditation and issue certificates, as required in NELAC, Chapter four, to an applicant laboratory within 30 calendar days of receipt of the laboratory's application.
- c) All fees shall be paid by laboratories as required by the NELAP-recognized secondary accrediting authority.

- d) Laboratories seeking NELAP accreditation by a NELAP-recognized secondary accrediting authority shall not be required to meet any additional proficiency testing, quality assurance, or on-site assessment requirements for the fields of testing for which the laboratory holds primary NELAP accreditation.
- e) If a NELAP-recognized secondary accrediting authority notes any potential nonconformance with the NELAC standards by a laboratory during the initial application process for reciprocal accreditation, or for a laboratory that already has been granted NELAP accreditation through reciprocity, the NELAP-recognized secondary accrediting authority shall immediately notify, in writing, the applicable NELAP-recognized primary accrediting authority and the laboratory. However, the laboratory is to be notified only in situations where no administrative or judicial prosecution is contemplated. The notification must cite the applicable sections within the NELAC standards for which nonconformance by the laboratory has been noted.
  - 1) If the alleged nonconformance is noted during the initial application process for reciprocal NELAP accreditation, final action on the application for reciprocal NELAP accreditation shall not be taken until the alleged nonconformance issue has been resolved, or
  - 2) If the alleged nonconformance is noted after reciprocal NELAP accreditation has been granted, the laboratory shall maintain its current NELAP accreditation status until the alleged nonconformance issue has been resolved.
- f) Upon receipt of the subsection 6.2.1(e) notification, the NELAP-recognized primary accrediting authority shall:
  - 1) Review and investigate the alleged nonconformance,
  - 2) Take appropriate action on the laboratory as set forth by the NELAC standards, including the addition of any change of accreditation status in the National Environmental Laboratory Accreditation Database. All such actions shall be taken in accordance with the laboratory's right to due process as set forth in the NELAC standards, Chapter four, Accreditation Process,
  - 3) Respond to the NELAP-recognized secondary accrediting authority, in writing, with a copy to the NELAP Director, within 20 calendar days of receipt of the subsection 6.2.1(e) notification providing:
    - A) an initial report of the findings;
    - B) a description of the actions to be taken; and
    - C) a schedule for implementation of further action on the alleged nonconformance, if necessary.
- g) If, in the opinion of the secondary accrediting authority, the primary accrediting authority does not take timely and appropriate action on the complaint, the secondary accrediting authority should notify the NELAP Director of the dispute between the two accrediting authorities regarding proper disposition of the complaint. Within 20 calendar days of receipt of such notification, the NELAP Director shall review the alleged nonconformance and take appropriate action according to the standards set forth in this Chapter.

## **6.2.2 Where to Apply for NELAP Accreditation**

- a) Laboratories that are NELAP accredited by an accrediting authority that has lost NELAP recognition may seek NELAP accreditation through any NELAP-recognized accrediting authority. The laboratory's NELAP accreditation shall remain valid throughout its current certificate of accreditation.

- b) Except for governmental laboratories as noted in subsection 6.2.2(d) below, all laboratories seeking NELAP accreditation or renewal of NELAP accreditation must apply for such accreditation through their home state (the state in which the laboratory facility is located) accrediting authority.
- c) Laboratories located in a territory or other state that is not NELAP-recognized may seek NELAP accreditation through any NELAP-recognized accrediting authority.
- d) Governmental laboratories that are organizational units of the same department or agency in which the accrediting authority is located or have other institutional conflicts of interest shall:
  - 1) demonstrate by organizational structure that the laboratory's Technical Director and the environmental laboratory accreditation program manager do not report within the same chain-of-command; and
  - 2) demonstrate by policies and procedures that conflicts-of-interest, actual or potential, do not exist; or
  - 3) apply for NELAP accreditation through any other NELAP-recognized accrediting authority.
- e) In order that all laboratory applications for NELAP accreditation are treated equally, accrediting authorities shall initiate processing applications for NELAP accreditation in the chronological order that the applications are received.

### **6.2.3 Documentation Maintained by Accrediting Authorities**

- a) The accrediting authority shall provide through publication, electronic media or other means a document or documents describing its environmental laboratory accreditation program.
  - 1) The document or documents shall include the following:
    - A) information setting forth the authority of the accrediting authority to grant laboratory accreditations and whether such laboratory accreditation is mandatory or voluntary;
    - B) information setting forth the accrediting authority's requirements for an environmental laboratory to become accredited;
    - C) information stating the requirements for granting, maintaining, withdrawing, suspending or revoking laboratory accreditation;
    - D) information about the laboratory accreditation process;
    - E) information on fees charged to applicants and accredited laboratories;
    - F) information regarding the rights and duties of accredited laboratories; and
    - G) information listing its NELAP accredited laboratories describing the NELAP accreditation granted.
  - 2) The document or documents shall be reviewed annually. A written record of this review must be available for inspection by the NELAP assessment team.
- b) When the document or documents reviewed in subsection 6.2.3(a)(2) above reveals that the accrediting authority's environmental laboratory accreditation program has changed or is otherwise different from



the accreditation program described in such documents, the document or documents shall be updated within 30 calendar days of the review.

- c) The document or documents described in subsection 6.2.3(a)(1) above shall be made readily available upon request.
- d) The accrediting authority shall have arrangements, consistent with NELAC, Chapter three, On-Site Assessment to safeguard information claimed by the laboratories as confidential.

### **6.3 APPLICATION FOR NELAP RECOGNITION**

This section describes the process by which accrediting authorities may apply for NELAP recognition and the procedures that NELAP will use to review the applications.

#### **6.3.1 Written Application for NELAP Recognition**

- a) Each accrediting authority requesting initial NELAP recognition shall complete an application and supply all supporting documentation. Applications can be obtained from the Office of the NELAP Director, USEPA.
- b) The application shall request information that is essential for the NELAP to evaluate an accrediting authority's environmental laboratory accreditation program. When documentation is required, copies of the applicable statutes, rules, regulations, policy statements, standard operating procedures, guidance documents, etc. must be submitted along with a clear citation of where the required information is found in the documents. The application will request the following information and documentation from the accrediting authority:
  - 1) the name, mailing address, telephone number, electronic mail address and telefacsimile number of the accrediting authority;
  - 2) the statutes and regulations establishing and governing the accrediting authority's environmental laboratory accreditation program as required in subsection 6.3.3.1 (b) and (c);
  - 3) the policies, guidance documents, promulgating instructions and standard operating procedures governing the operation of the accrediting authority's environmental laboratory accreditation program as set forth in subsection 6.3.3.1 ;
  - 4) the accrediting authority's arrangements for liability insurance and workman's compensation assurance coverage as required in subsection 6.3.3.1 (d);
  - 5) the requirements governing how the accrediting authority restricts the use of its accreditation by accredited laboratories as required in Section 6.8;
  - 6) the fields of testing for which the accrediting authority is requesting NELAP recognition;
  - 7) the name and title of the primary person responsible for the day-to-day management of the accrediting authority's environmental laboratory accreditation program as required in subsection 6.3.3.1 (h);
  - 8) the names, education and experience levels of the accrediting authority's environmental laboratory accreditation program's management and technical staff as required in subsection 6.3.3.1 (f), (g) and (h);

- 9) the names and contractual agreements for any external assessment bodies used by the accrediting authority as required in subsection 6.3.3.1.2 and 6.3.3.1.3 (b)(3);
  - 10) the names, areas of responsibility, education and experience levels of all technical and assessment employees of any external assessment bodies used by the accrediting authority as required in subsection 6.3.3.1.2 and 6.3.3.1.3 (b)(3);
  - 11) RESERVED
  - 12) a description of the accrediting authority's environmental laboratory accreditation program quality systems (e.g., a quality systems manual or a quality assurance plan) as required in subsection 6.3.3.1.3;
  - 13) the procedures for the selecting, training, contracting and appointing of the accrediting authority's laboratory assessors as required in subsection 6.3.3.1 (f) and (g);
  - 14) a description of the accrediting authority's conflict-of-interest disclosure program as required in subsection 6.3.3.1 (i);
  - 15) a tabular listing of all laboratories applying for accreditation in the two-year period immediately preceding the date of the application. The table shall set forth the date on which the laboratory's application for accreditation was received by the accrediting authority and the date on which final action on the application was taken.
  - 16) the policies and procedures used by the accrediting authority for establishing and maintaining records on each accredited laboratory and procedures for record access and retention as required in subsection 6.3.3.1.1;
  - 17) the accrediting authority's findings, reports and corrective actions from internal audits conducted in the last two years as required in subsection 6.3.3.1 (j) and 6.3.3.1.3 (b)(4);
  - 18) a certification that the accrediting authority meets the provisions of Section 6.2 of this Chapter;
  - 19) the name and job title of the individual or individuals authorized to sign accreditation certificates; and
  - 20) the standardized checklist required by subsection 6.3.2 (c)(1) is to be completed by the applicant accrediting authority citing the location in the application or supporting documents where the checklist information is provided.
- c) The application must be signed and dated by the highest ranking individual within the department or agency responsible for laboratory accreditation activities for which NELAP recognition is being sought. By signature on the application, this individual must attest to the validity of the information contained within the application and its supporting documents.
- d) The accrediting authority shall submit a renewal application to the NELAP every two years to maintain NELAP recognition.
- 1) The NELAP shall send by certified mail or some other verifiable means to the accrediting authority, no later than 180 calendar days prior to the expiration of the accrediting authority's then-current NELAP recognition an application for renewal of NELAP recognition to the accrediting authority. This notification of renewal shall indicate whether an on-site assessment is due as set forth in subsection 6.4 (a).

- 2) The accrediting authority must address each requirement of subsection 6.3.1 (b); however, it must submit information and documentation only of changes from the accrediting authority's most recent NELAP-recognized environmental laboratory accreditation program.
- 3) The accrediting authority must submit the completed renewal application and supporting documents to the NELAP within 30 calendar days of receiving the renewal notification.

### **6.3.2 Application Completeness Review by NELAP**

- a) The NELAP is required to provide notices required by this Chapter only to those accrediting authorities who have submitted an initial application for NELAP recognition or who hold NELAP recognition.
- b) If the NELAP does not receive a completed renewal application as specified in subsection 6.3.1 (d)(3), the accrediting authority shall be notified in writing. If the accrediting authority does not submit the completed application within 20 calendar days of receipt of this notification from the NELAP, the accrediting authority's NELAP recognition will not be renewed upon expiration of its current NELAP recognition.
- c) Following receipt of an initial or a renewal application, the NELAP must complete a review of the application and supporting documents to determine that information and supporting documentation required in subsection 6.3.1 (b) is included with the submittal.
  - 1) The completeness review of the application and supporting documents shall be conducted using a standardized checklist provided by the NELAP as part of the application. The checklist shall be designed to assist the applicant in gathering all the information needed to complete the application and include a place to note the date the completeness review was completed.
  - 2) The NELAP must notify the accrediting authority in writing within 20 calendar days of receiving the application of any additional information needed to complete the application.
  - 3) The accrediting authority must provide any additional information or clarification requested in writing within 20 calendar days of receipt of the 6.3.2(c)(2) notification.
    - A) The NELAP may grant extensions to the 20-day time period for up to an additional 20 calendar days if the accrediting authority requests the extension in writing.
    - B) The NELAP shall notify the accrediting authority in writing when an extension is granted.
  - 4) Written notification to the accrediting authority that an application is complete shall be furnished by the NELAP within seven calendar days of the date of such determination.

### **6.3.3 Application Technical Review by a NELAP Assessment Team**

- a) Within 30 calendar days of the determination that the application is complete, the NELAP assessment team as established in subsection 6.9.1 will perform a technical review of the application and its supporting documents and respond in writing to the accrediting authority.
  - 1) The review shall be conducted in accordance with the NELAP standard operating procedures for application review; and
  - 2) The review shall be performed by the same NELAP assessment team assigned to conduct the on-site assessment.

- 3) In the years when no on-site assessment is required, as provided in subsection 6.4 (a)(2), the NELAP Director shall endeavor to appoint the same NELAP assessment team that conducted the application technical review and on-site assessment for the accrediting authority's immediately preceding application cycle.
  - 4) The NELAP Director shall appoint a different NELAP assessment team for each succeeding four-year NELAP on-site assessment cycle as set forth in Section 6.4 (a) of this Chapter. New four-year NELAP on-site assessment cycles shall start with each renewal application when an on-site assessment of the accrediting authority is required.
- b) The NELAP assessment team will review the application and supporting documents to evaluate whether the accrediting authority's environmental laboratory accreditation program requires its accredited laboratories to meet the standards set forth by the NELAC standards, Chapter two, Proficiency Testing, Chapter three, On-Site Assessment, Chapter four, Accreditation Process and Chapter five, Quality Systems.
  - c) Should the NELAP assessment team have questions or need additional application information to determine the accrediting authority's compliance with this Chapter, the NELAP assessment team must seek additional application information and documentation from the accrediting authority.

#### **6.3.3.1 Required Technical Elements of a NELAP-Recognized Accrediting Authority's Program**

- a) The NELAP assessment team will review the application and supporting documentation to ensure that the accrediting authority's environmental laboratory accreditation program meets the requirements of subsection (b) through (m) below.
- b) The accrediting authority shall be a legally identifiable governmental entity;
- c) The accrediting authority shall have the authority, rights and responsibilities necessary to carry out an environmental laboratory accreditation program;
- d) The accrediting authority shall have the same arrangements to cover liabilities and workman's compensation claims arising from its operations and activities as all other programs, units, divisions, bureaus, etc. in the department or agency in which the accrediting authority is located;
- e) The accrediting authority shall have financial stability and the physical and human resources required for the operation of an accrediting authority's laboratory accreditation program. The accrediting authority shall have and make available on request a description of the means by which it receives its financial support. As a benchmark, the accrediting authority shall have the resources necessary to complete action on a laboratory's application within nine months from the time a completed application is first received from the laboratory. This time period applies as long as all turn-around times for responses to application review, proficiency testing and on-site assessment issues are carried out within the required time limits set forth in the NELAC standards.
- f) The accrediting authority shall appoint and maintain records on assessors, including contractual assessors, who meet the education, experience and training requirements set forth in the NELAC standards, Chapter three, On-Site Assessment. Such records shall include:
  - 1) name and address;
  - 2) organization affiliation and position held;
  - 3) educational qualification and professional status;

- 4) work experience;
  - 5) training applicable to laboratory accreditation;
  - 6) experience in laboratory assessment, together with field of competence; and
  - 7) date of most recent updating of record.
- g) The accrediting authority shall have a system in place to evaluate assessor performance that is consistent with the organizational employee evaluation program and demonstrates compliance with the NELAC standards, Chapter three, On-Site Assessment;
- h) The accrediting authority shall identify one individual responsible for day-to-day management of the accrediting authority's environmental laboratory accreditation program. This individual must:
- 1) be an employee of the accrediting authority, and
  - 2) have the technical expertise necessary to:
    - A) plan and manage the laboratory accreditation program,
    - B) coordinate various facets of the laboratory accreditation program with other territory, state and federal accrediting authorities,
    - C) coordinate development of environmental laboratory accreditation regulations, and
    - D) evaluate the technical competence and performance of contractors or employees.
- i) The accrediting authority shall have arrangements to ensure that the accrediting authority's management and technical staff are free of any commercial, financial or other pressures that influence the results of the accreditation process and are subject to the same conflict of interest disclosure requirements designed to identify and eliminate potential conflict-of-interest problems as all other programs, units, divisions, bureaus etc. in the department or agency in which the accrediting authority is located;
- j) The accrediting authority shall have a documented procedure in place to conduct systematic internal audits annually of the accrediting authority's environmental laboratory accreditation program to verify compliance with the NELAC standards. One element of the annual internal audit shall be to review the effectiveness of the quality systems required in subsection 6.3.3.1.3. When applicable, the accrediting authority shall use the same policies and procedures for internal audits as used by all other programs, units, divisions, bureaus etc. in the department or agency in which the accrediting authority is located;
- k) The accrediting authority shall designate the individual specified in subsection 6.3.3.1 (h) or an individual who reports directly to the individual responsible for day-to-day management of the accrediting authority's environmental laboratory accreditation program to take responsibility for the quality system and maintenance of the quality documentation required in subsection 6.3.3.1.3;
- l) The accrediting authority shall have established standard operating procedures for dealing with appeals, complaints and disputes arising from denial, suspension or revocation of laboratory accreditation, or from users of the services about the NELAP accredited laboratories or any other matters,

- m) The accrediting authority shall require NELAP-accredited laboratories to participate in a proficiency testing program meeting the requirements of the NELAC standards, Chapter two, Proficiency Testing, Appendix A; and
- n) The accrediting authority or its contractors shall not offer consultancy or other services which may compromise the objectivity or impartiality of its accreditation process and decisions.

#### **6.3.3.1.1 Records**

- a) The accrediting authority shall have arrangements to establish and maintain records for each accredited laboratory with respect to all aspects of the laboratory's accreditation process.
- b) The accrediting authority shall have a policy and procedure for retaining NELAP accreditation records for a minimum of ten years or a longer period of time if required by contractual obligations or pertinent territorial, state or federal laws and regulations.
- c) The accrediting authority shall have a policy and procedures concerning access to records as prescribed by the territorial, state or federal entity in which the accrediting authority resides.
- d) The accrediting authority shall have a policy and procedure for updating the NELAP national database with the NELAP-required information specific to the laboratories for which that accrediting authority is the primary or secondary accrediting authority. These updates must occur within the following time-frames:
  - 1) daily for those accrediting authorities with an automated e-mail system or automated batch processing that occurs even when the system is unattended, or
  - 2) weekly for those accrediting authorities that are posting interactively.

#### **6.3.3.1.2 Use of Contractors by an Accrediting Authority**

- a) The accrediting authority shall have arrangements to ensure and require by signed contract or other similar type of binding document that all laboratory accreditation functions performed by a contractor on behalf of the accrediting authority are carried out in compliance with the NELAC standards.
- b) When laboratory accreditation functions are contracted out, the accrediting authority shall:
  - 1) take full responsibility for such contracted work,
  - 2) ensure that the contractor and their employees are competent and comply with the applicable provisions of the NELAC standards,
  - 3) ensure that the contractor and their employees comply with the confidentiality requirements of the accrediting authority and NELAC, and
  - 4) ensure that the contractor and their employees are not directly involved with:
    - A) the laboratory seeking NELAP accreditation from the accrediting authority employing the contractor; or
    - B) any other affiliations which would compromise impartiality in the NELAP laboratory accreditation process.

#### **6.3.3.1.3 Accrediting Authority's Quality System**

- a) The accrediting authority shall have a quality system appropriate to the type, range and volume of work performed by the accrediting authority.
- b) The quality system shall be documented in a quality manual and associated written quality procedures and shall be made available for use by the staff. The quality manual shall include at least the following:
  - 1) the quality policy statement, including objectives and commitments, signed by the manager responsible for day-to-day management of the accrediting authority's environmental laboratory accreditation program;
  - 2) the organizational structure of the accrediting authority's environmental laboratory accreditation program and the responsibilities of individual staff assigned to the structure;
  - 3) the policies and procedures for acquiring, training, supervising and evaluating the performance of contractors carrying out any part of the accrediting authority's laboratory accreditation program;
  - 4) the arrangements for annual internal audits, including Quality System reviews, as required in subsection 6.3.3.1 (j);
  - 5) the system for providing feedback to personnel responsible for the area audited and for taking timely and appropriate corrective actions whenever discrepancies are detected;
  - 6) the procedures established to address conflict-of-interest questions arising from the NELAC standards as set forth in subsection 6.2.2 (d)(2) and for the accrediting authority's management and technical staff as set forth in subsection 6.3.3.1 (i);
  - 7) the policies and procedures established to maintain document control for documents required by the NELAC standards;
  - 8) the policies and procedures to implement the accreditation process; and
  - 9) the policies and procedures for dealing with appeals, complaints and disputes by laboratories.

#### **6.3.3.2 Application Technical Review Report**

- a) The NELAP assessment team will accept an initial application and its supporting documentation for continued processing that contains sufficient information to determine that an accrediting authority meets the requirements of the NELAC standards for designation as a NELAP-recognized accrediting authority. When the NELAP assessment team completes its review of an initial application and notes no deficiencies, the NELAP assessment team will schedule the on-site assessment as set forth in subsection 6.4.1 below.
- b) The NELAP assessment team will accept a renewal application and its supporting documentation for continued processing that contains sufficient information to determine that an accrediting authority meets the requirements of the NELAC standards for designation as a NELAP-recognized accrediting authority. When the NELAP assessment team completes its review of a renewal application and denotes no deficiencies, the NELAP assessment team will recommend to the NELAP Director that NELAP recognition be maintained.

- c) Except as noted in Section 6.5, the NELAP assessment team will not accept the application for continued processing if it notes deficiencies. The NELAP assessment team will send by certified mail an application technical review report to the accrediting authority. The report will:
  - 1) identify any specific deficiencies noted during the application technical review,
  - 2) include references to the specific NELAC standards, and
  - 3) provide suggested corrective action.
- d) To proceed with the review process, the accrediting authority shall respond with written corrective actions within 30 calendar days of receipt of the NELAP assessment team's subsection 6.3.3.2(c) notification. The NELAP assessment team will review the corrective actions within 30 calendar days of receipt of the accrediting authority's response. Alternately, the accrediting authority has the option to withdraw all or part of its NELAP recognition request.
  - 1) If the corrective actions submitted by the accrediting authority do not meet the requirements of this Chapter, the NELAP assessment team will notify the accrediting authority that it must submit additional corrective actions within 20 calendar days of receipt of the NELAP assessment team's response. The NELAP assessment team will review the accrediting authority's second corrective action response within 20 calendar days of receipt.
  - 2) If the second corrective action response submitted by the accrediting authority does not address satisfactorily all of the application deficiencies, the NELAP assessment team will make no further suggestions to the accrediting authority for correction of application deficiencies.
  - 3) If application deficiencies still remain after the assessment team's second attempt to resolve those deficiencies, the NELAP assessment team will document those deficiencies which are not resolved and recommend to the NELAP Director that:
    - A) the accrediting authority's application for initial NELAP recognition be denied; or
    - B) the accrediting authority's NELAP recognition be revoked.
- e) If the initial application as submitted contained no deficiencies or if deficiencies were corrected as provided in subsection 6.3.3.2(d), except those deficiencies requiring legislative or rulemaking action as set forth in Section 6.5, the NELAP assessment team will schedule the on-site assessment as set forth in subsection 6.4.1 below.
- f) If an accrediting authority elects to appeal denial or revocation of NELAP recognition resulting from the Section 6.3.3 application technical review process, an accrediting authority must follow the procedure set forth in Section 6.10 of this Chapter.
- g) After review of the renewal NELAP-recognition application and supporting documents, the NELAP assessment team will schedule an on-site assessment of the accrediting authority's environmental laboratory accreditation program as set forth in Section 6.4 (a) and subsection 6.4.1 (a) below.

#### **6.3.4 Notification of Changes to An Accrediting Authority's Program**

- a) For all changes in the accrediting authority's environmental laboratory accreditation program listed below, the NELAP Director shall be notified of changes to:



- 1) the authority to accredit laboratories as stated in the statutes, regulations and promulgating instructions establishing and governing the accrediting authority's environmental laboratory accreditation program,
  - 2) the organizational structure,
  - 3) the rules, regulations, policies, guidance documents and standard operating procedures,
  - 4) the mailing address and office location, telephone and telefacsimilie numbers and electronic mail address, and
  - 5) the contractual arrangements, including contractor's personnel, for laboratory accreditation activities contracted out under authority of subsection 6.2 (c).
- b) The notification to the NELAP Director shall be made within 30 calendar days of the change taking place in the accrediting authority's environmental laboratory accreditation program.
- c) The NELAP Director may request further documentation or conduct on-site assessments to verify that changes in the accrediting authority's NELAP-recognized environmental laboratory accreditation program do not place that program in violation of the NELAC standards.

#### **6.4 ON-SITE ASSESSMENT OF THE ACCREDITING AUTHORITY**

- a) On-site assessments of an accrediting authority's environmental laboratory accreditation program shall be conducted on a four-year cycle as follows:
- 1) An initial on-site assessment shall be conducted in conjunction with an accrediting authority's initial application process and every four years thereafter; and
  - 2) No on-site assessment of an accrediting authority's environmental laboratory accreditation program is required for the two-year renewal application immediately following an application for NELAP recognition where an on-site assessment was conducted.
- b) The NELAP assessment team will arrange on-site assessments except as stated in subsection 6.4(c) below at the mutual convenience of the parties.
- c) The NELAP assessment team may make subsequent announced or unannounced on-site assessments of an accrediting authority's environmental laboratory accreditation program whenever such an assessment is necessary to determine the accrediting authority's compliance with the requirements of the NELAC standards.

##### **6.4.1 Scheduling the On-Site Assessments**

- a) The NELAP assessment team shall contact the accrediting authority to schedule on-site assessments as set forth in Section 6.4 (a) above within 20 calendar days of the date the NELAP assessment team accepts an initial or renewal application.
- b) The NELAP assessment team must send to the accrediting authority written confirmation of the logistics required to conduct the on-site assessment. The written confirmation shall include, but is not limited to:
- 1) on-site assessment date and agenda or schedule of activities,
  - 2) copies of the standardized assessment checklists,

- 3) the names, titles, affiliations, and on-site assessment responsibilities of the NELAP assessment team members, and
  - 4) the names and titles of all accrediting authority staff that need to be available during the on-site assessment.
- c) All on-site assessments shall be conducted no later than 50 calendar days following approval of the application.

#### **6.4.2 Conducting the On-Site Assessment**

- a) The purpose of the on-site assessment is to verify compliance with the requirements of the NELAC standards including, but not limited to:
- 1) determining the accuracy of information contained in the accrediting authority's application and supporting documents;
  - 2) determining whether the accrediting authority's implementation of its environmental laboratory accreditation program conforms with the information and data contained in the application and supporting documents; and
  - 3) observing, upon recommendation of the NELAP assessment team and the approval of the NELAP Director, an accrediting authority's laboratory assessor(s) conducting an on-site assessment of a laboratory seeking initial or renewal NELAP accreditation. The NELAP assessment team members shall not participate in the laboratory's assessment.
- b) When conducting an on-site assessment, the NELAP assessment team shall, at a minimum:
- 1) review the accrediting authority's record keeping and documentation procedures;
  - 2) conduct interviews with the accrediting authority's management and technical staff;
  - 3) review selected laboratory accreditation cases;
  - 4) review records of laboratory complaints, disputes and appeals; and
  - 5) review quality assurance and internal audit procedures employed by the accrediting authority.
- c) The NELAP assessment team shall have access to all records of the accrediting authority's environmental laboratory accreditation program to determine compliance with the NELAC standards.
- d) The NELAP assessment team shall have the opportunity to interview privately:
- 1) all management and technical staff of the accrediting authority's environmental laboratory accreditation program; and
  - 2) any NELAP-accredited laboratory receiving its accreditation from the applicant accrediting authority.
- e) The NELAP assessment team must ensure that the assessment is conducted according to the schedule as set forth in subsection 6.4.1 (b)(1) and consists of the following:
- 1) an opening meeting,

- 2) the physical assessment of the accrediting authority's environmental laboratory accreditation program, and
  - 3) an exit interview to discuss all noted deficiencies.
- f) The NELAP assessment team shall conduct all assessments in accordance with the NELAP standard operating procedure for conducting on-site assessments of accrediting authorities.

#### **6.4.3 On-Site Assessment Reports**

- a) The NELAP assessment team will send by certified mail to the accrediting authority an on-site assessment report within 30 calendar days of completion of the on-site assessment. The report shall include, but is not limited to:
- 1) the date(s) of assessment;
  - 2) the name(s) of the person(s) responsible for the report;
  - 3) the NELAP recognition fields of testing being applied for; and
  - 4) the comments of the NELAP assessment team on the accrediting authority's compliance with the requirements of the NELAC standards.
- b) If the on-site assessment does not reveal any deficiencies, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority be granted or maintain NELAP recognition.
- c) If deficiencies are noted during the on-site assessment, the report will:
- 1) identify any specific deficiencies noted during the on-site assessment,
  - 2) include references to the specific NELAC standards, and
  - 3) provide suggested corrective action.
- d) If the on-site assessment reveals deficiencies, the accrediting authority shall submit a plan of corrective action to the NELAP assessment team within 30 calendar days of receipt of the on-site assessment report.
- 1) The plan of corrective action must detail those specific actions taken or that will be taken by the accrediting authority to correct all deficiencies noted by the NELAP assessment team during the on-site assessment.
  - 2) The plan of corrective action must include the accrediting authority's projected time to complete the corrective actions not yet complete at the time of the accrediting authority's response to the on-site assessment report.
  - 3) Except for those deficiencies set forth in Section 6.5, the implementation of corrective actions must take place no more than 65 calendar days from receipt of the on-site assessment report.
- e) The NELAP assessment team shall recommend to the NELAP Director revocation or denial of NELAP recognition for on-site assessment deficiencies for any accrediting authority that fails to submit a plan of corrective action within 30 calendar days as set forth in subsection 6.4.3(d) above.

- f) Within 20 calendar days of receipt of the accrediting authority's plan of corrective actions, the NELAP assessment team shall review the plan and respond in writing to the accrediting authority.
  - 1) If the accrediting authority corrects all deficiencies, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority be granted or maintain NELAP recognition.
  - 2) If the accrediting authority's plan of corrective actions does not address all deficiencies, the NELAP assessment team will notify the accrediting authority by certified mail that it must submit another plan of corrective actions for the remaining deficiencies not covered by Section 6.5 within 20 calendar days of the accrediting authority's receipt of this notification.
- g) The NELAP assessment team shall review the corrective actions for the remaining deficiencies within 20 calendar days of receipt of a subsection 6.4.3(f)(2) response from the accrediting authority.
  - 1) If all deficiencies are not corrected and the remaining deficiencies affect only certain fields of testing, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority's NELAP recognition be denied or revoked for those fields of testing for which on-site assessment deficiencies remain.
  - 2) If all deficiencies are not corrected and the remaining deficiencies affect the entire accrediting authority's environmental laboratory accreditation program, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority's NELAP recognition be denied or revoked.
  - 3) If the only remaining deficiencies require legislation or rulemaking as set forth in Section 6.5, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority be granted or maintain NELAP recognition.
  - 4) If remaining deficiencies are corrected, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority be granted or maintain NELAP recognition.
- h) If the NELAP assessment team determines that the accrediting authority has falsified information included in its application and supporting documents, the NELAP assessment team shall recommend to the NELAP Director that the accrediting authority's NELAP recognition be denied or revoked.

#### **6.5 ACCREDITING AUTHORITY'S REQUEST FOR EXTENSION OF TIME TO COMPLY WITH THE NELAC STANDARDS**

- a) For all accrediting authorities applying for NELAP recognition prior to July 1, 2000, and upon written request to the NELAP Director, through the NELAP assessment team, an extension of time, not to exceed two years, to correct deficiencies noted in the accrediting authority's application and/or deficiencies noted during the on-site assessment will be granted only:
  - 1) when an applicant accrediting authority has an operating environmental laboratory accreditation program for the fields of testing for which it is seeking or renewing NELAP recognition, and
  - 2) when implementation of corrective actions to correct application and/or assessment deficiencies requires the accrediting authority to promulgate new or revised regulations, or
  - 3) when implementation of corrective actions to correct application and/or assessment deficiencies requires the accrediting authority to seek new or revised legislation.

- b) If the deficiencies continue to exist after two years from the date the extension was granted, the NELAP recognition granted as set forth in subsection 6.4.3 (g)(3) above will not be renewed.
- c) The accrediting authority shall include in its request for an extension of time to comply with the NELAC standards a projected time table for correction of the application and/or assessment deficiencies.
- d) For an accrediting authority seeking initial NELAP recognition on or after July 1, 2000, all NELAC requirements must be met prior to being granted NELAP recognition.
- e) Regardless of the date on which applications for renewal of NELAP recognition of an accrediting authority are submitted, the extension of time provisions to correct deficiencies set forth in Section 6.5 of this Chapter shall remain in effect provided those deficiencies were caused by changes to the NELAC standards.

## **6.6 NELAP ASSESSMENT TEAM RECOMMENDATIONS TO THE NELAP DIRECTOR**

- a) All recommendations required by this Chapter from the NELAP assessment team to the NELAP Director must be made in writing.
- b) All NELAP assessment team recommendations to the NELAP Director shall include the following documentation when applicable:
  - 1) a recommendation to grant, maintain or revoke NELAP recognition in full or in part;
  - 2) a summary of the reasons supporting the recommendation;
  - 3) a copy of all application review letters sent to the accrediting authority and all corrective action response letters submitted by the accrediting authority to the NELAP assessment team;
  - 4) a copy of all on-site assessment review letters sent to the accrediting authority and all corrective action response letters submitted by the accrediting authority; and
  - 5) a copy of the accrediting authority's requests for extension of time to implement corrective actions if legislative or additional rulemaking is required pursuant to Section 6.5.
- c) A copy of any NELAP assessment team's recommendation to the NELAP Director also shall be furnished to the accrediting authority.
- d) Within 20 calendar days of receipt of the NELAP assessment team's recommendation, the NELAP Director shall provide written notification to the accrediting authority of acceptance or rejection of the NELAP assessment team's recommendation.
- e) The accrediting authority has the option to appeal a revocation or denial decision regarding NELAP recognition by the NELAP Director as set forth in Section 6.10 of this Chapter.

## **6.7 CERTIFICATE OF RECOGNITION TO THE ACCREDITING AUTHORITY**

- a) The NELAP Director will issue a certificate of NELAP recognition dated the day on which NELAP recognition is granted.
- b) The certificate of NELAP recognition shall include the following items:
  - 1) the name and address of the accrediting authority,

- 2) the fields of testing for which the accrediting authority is NELAP-recognized,
- 3) the date of the accrediting authority's most recent on-site assessment,
- 4) the expiration date of the accrediting authority's NELAP recognition which shall not be more than two years from the date of the most recent date granting NELAP recognition,
- 5) the signature of the NELAP Director,
- 6) a statement that the accrediting authority is in compliance with the NELAC standards,
- 7) a statement that the accrediting authority has been granted the authority to accredit environmental laboratories for the fields of testing for which the accrediting authority is NELAP-recognized,
- 8) a statement that continued NELAP recognition depends on compliance with the NELAC standards;
- 9) a seal incorporating the NELAP insignia; and
- 10) a unique designator, such as date of issuance and a serial or certificate number.

#### **6.8 USE OF ACCREDITATION BY NELAP ACCREDITED LABORATORIES**

- a) The accrediting authority shall have requirements for controlling the ownership, use and display of the accrediting authority's NELAP accreditation documents and for controlling the manner in which an accredited laboratory may refer to its NELAP accreditation and/or use of the NELAC/NELAP logo. These arrangements shall include, but are not limited to requirements that:
  - 1) NELAP accredited laboratories post or display their most recent NELAP accreditation certificate or their NELAP-accredited fields of testing in a prominent place in the laboratory facility;
  - 2) NELAP accredited laboratories make accurate statements concerning their NELAP accreditation fields of testing and NELAP accreditation status;
  - 3) NELAP accredited laboratories accompany the accrediting authority's name and/or the NELAC/NELAP logo with at least the phrase "NELAP accredited" and the laboratory's accreditation number or other identifier when the accrediting authority's name is used on general literature such as catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials; and
  - 4) NELAP accredited laboratories not use their NELAP certificate, NELAP accreditation status and/or NELAC/NELAP logo to imply endorsement by the accrediting authority.
- b) The accrediting authority shall have arrangements to ensure that NELAP accredited laboratories choosing to use the accrediting authority's name, making reference to its NELAP accreditation status and/or using the NELAC/NELAP logo in any catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials, the NELAP accredited laboratory shall:
  - 1) distinguish between proposed testing for which the NELAP-accredited laboratory is accredited and the proposed testing for which the NELAP accredited laboratory is not accredited;
  - 2) include the NELAP-accredited laboratory's accreditation number or other identifier; and

- c) The accrediting authority shall have arrangements to ensure that the NELAP-accredited laboratories upon suspension, revocation or withdrawal of their NELAP accreditation shall:
  - 1) discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical results or other materials that contain reference to their past NELAP accreditation status and/or display the NELAC/NELAP logo, and
  - 2) return any certificates for NELAP accreditation to the accrediting authority.
- d) The accrediting authority shall have arrangements to take suitable actions, including legal action, when incorrect references to the accrediting authority's NELAP accreditation, misleading use of the laboratory's NELAP accreditation status and/or unauthorized use of the NELAC/NELAP logo is found in catalogs, advertisements, business solicitations, proposals, quotations, laboratory analytical reports or other materials.

## **6.9 REQUIREMENTS OF THE NELAP**

- a) The NELAP assessment team shall submit all documents, letters, assessment notes, checklists, etc. to the NELAP headquarters office within:
  - 1) 30 calendar days of the final decision on the application by the NELAP Director, or
  - 2) 30 calendar days after the final recommendation by the Accrediting Authority Review Board (AARB) as set forth in Section 6.10 of this Chapter.
- b) The NELAP Director shall maintain complete and accurate records of all documents relating to the application and on-site assessment processes for each accrediting authority for a minimum of ten years or a longer period of time if required by contractual obligations or pertinent federal laws and regulations.
- c) The NELAP Director shall maintain an electronic directory to display the status of all NELAP-recognized accrediting authorities, pending applications for NELAP recognition and currently scheduled announced on-site assessments.

### **6.9.1 NELAP Assessment Team**

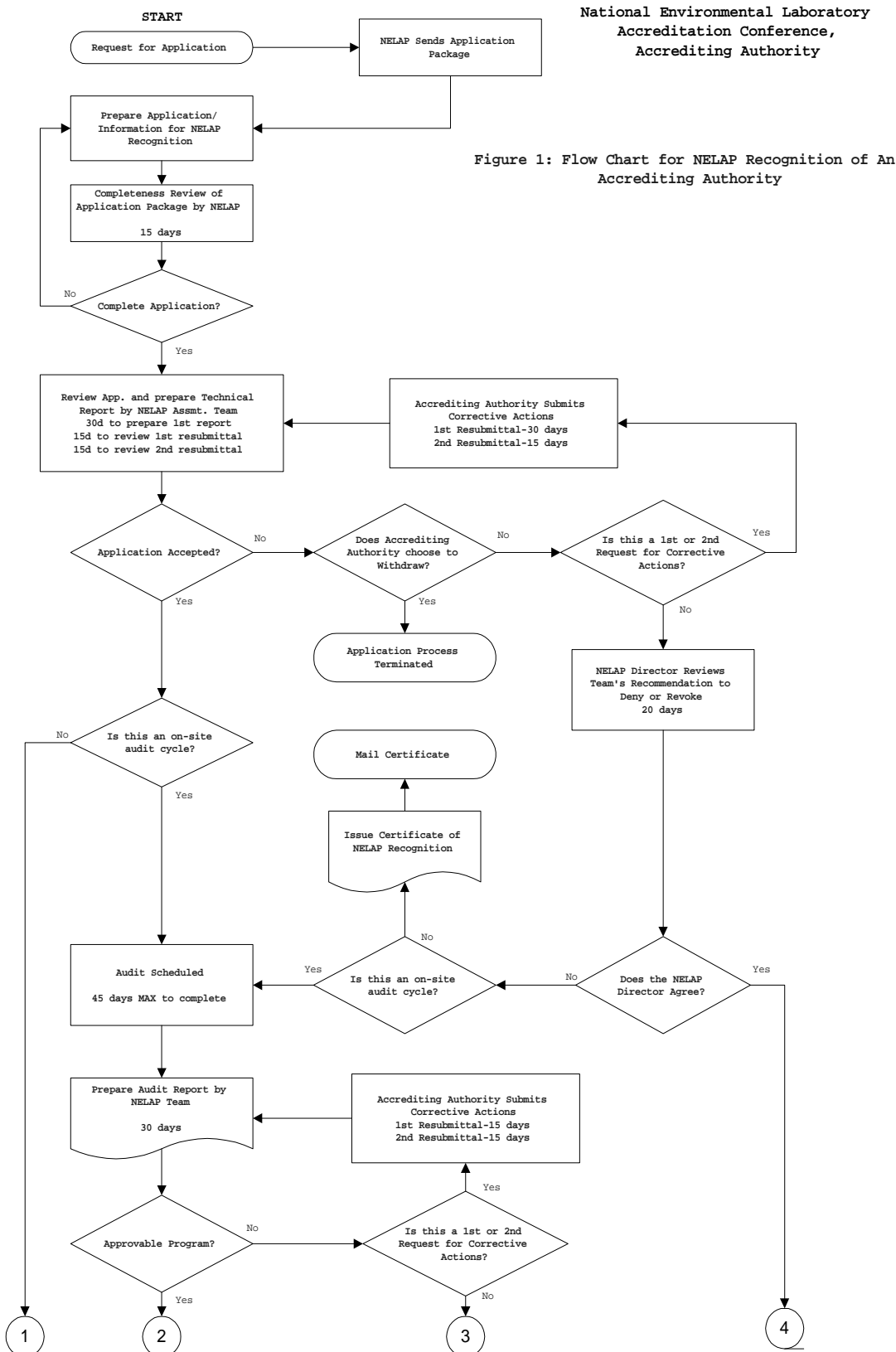
- a) The NELAP Director shall appoint NELAP assessment team members as set forth in Section 6.3.3 (a)(4) and delegate the responsibilities required by this Chapter to assessment teams.
- b) During the time prior to the NELAP issuing the first NELAP recognitions to accrediting authorities, the NELAP assessment team shall consist of at least one member who is an employee of the USEPA and at least one member who is an employee of another operating territorial, state or federal environmental laboratory accreditation program.
- c) No later than two years from the date that the first accrediting authority recognitions are announced, the NELAP assessment team shall consist of at least one member who is an employee of the USEPA and at least one member who is a employee of a NELAP-recognized accrediting authority.
- d) Prior to conducting the on-site assessment of an accrediting authority's program, at least one member of the NELAP assessment team shall complete the NELAP Accrediting Authority Assessor Training Course.
- e) The NELAP assessment team shall:

- 1) have at least one member of the NELAP assessment team who meets the education, experience and training requirements for laboratory assessors specified in the NELAC standards, Chapter three, On-Site Assessment; and
- 2) have at least another member with experience that includes at least one of the following:
  - A) certification as a management systems lead assessor (quality or environmental) from an internationally recognized auditor certification body;
  - B) one year of experience implementing federal or state laboratory accreditation rulemaking;
  - C) laboratory accreditation management; or
  - D) one year experience developing or participating in laboratory accreditation programs.
- 3) All experience required by this subsection must have been acquired within the five year period immediately preceding appointment as a NELAP assessment team member.

#### **6.10 APPEALING DECISIONS TO DENY OR REVOKE NELAP RECOGNITION**

- a) Within 20 calendar days of official notification of the NELAP action on an accrediting authority's application for NELAP recognition, the accrediting authority shall notify the NELAP Director and the Accrediting Authority Review Board (AARB) (as established in the NELAC standards, Chapter one, Policy and Structure) if the accrediting authority chooses to appeal the NELAP action.
- b) If any AARB member is not free of financial connection to the appealing accrediting authority, or is not free of any other relationship that would bias their review of the case, that AARB member shall be excluded from participating in deliberations on that appeal.
- c) The AARB shall carry out an independent review of the entire record (all application information, checklists, review notes, on-site assessment notes, letters, reports and any other data in the NELAP and NELAP assessment team files).
- d) The AARB must conduct interviews with the accrediting authority, the NELAP assessment team members and the NELAP Director. The AARB also may conduct interviews with other individuals deemed appropriate by the AARB.
- e) If the accrediting authority so desires, an opportunity for both the NELAP and the accrediting authority to appear before the AARB shall be granted. Such a meeting shall be held in the state of the appealing accrediting authority.
- f) The AARB must complete its review and render a final recommendation to the NELAP Director within 90 calendar days following receipt of the notice of appeal.
- g) The ultimate decision to grant, maintain, deny or revoke NELAP recognition remains with the NELAP Director. The NELAP Director shall notify the appealing accrediting authority of his/her decision within 20 calendar days of receipt of the recommendation from the AARB.
- h) Accrediting authorities shall be limited to one appeal for each application cycle.





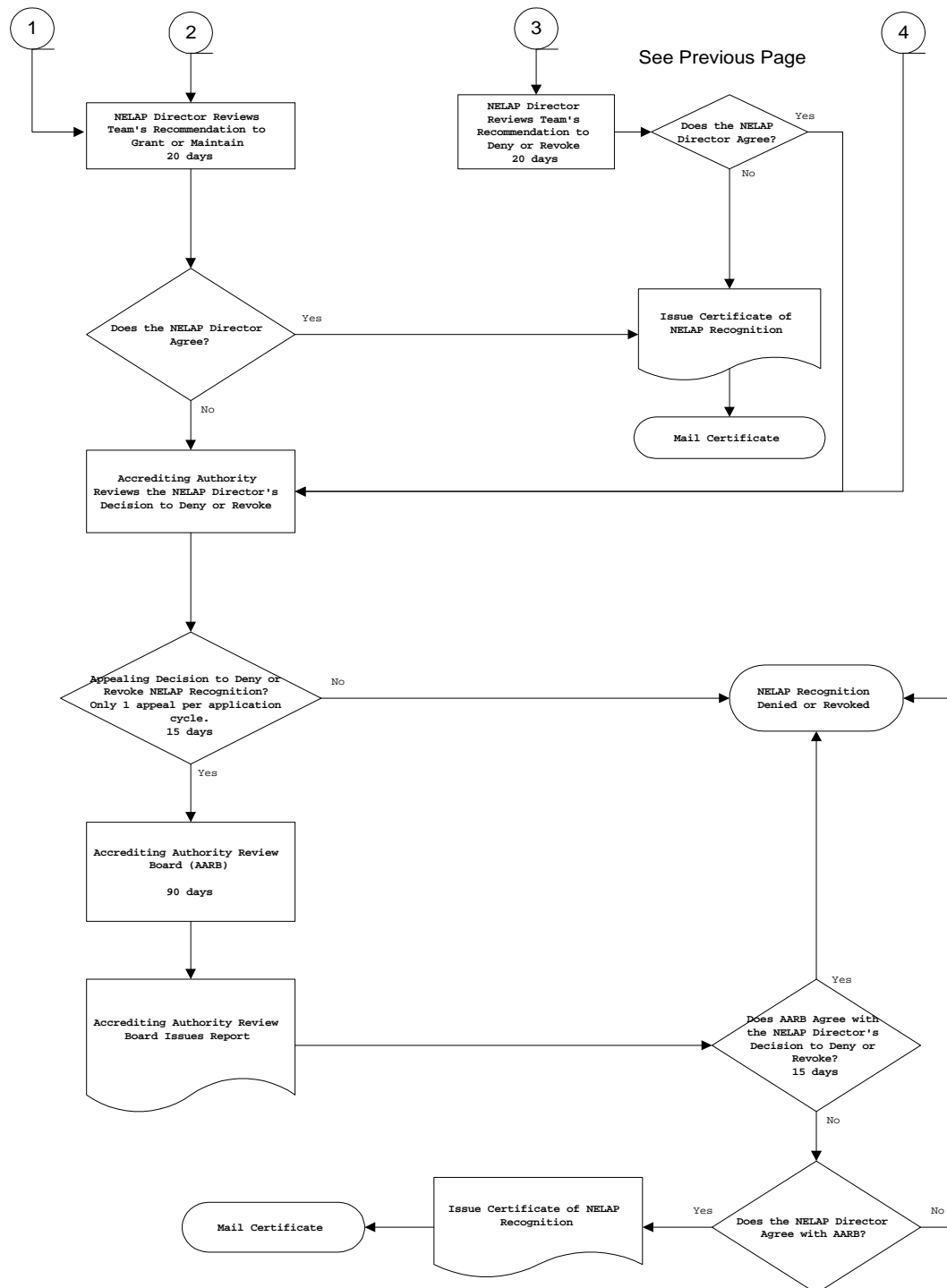


Figure 1: Flow Chart for NELAP Recognition of An Accrediting Authority